# ITEM 2: MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

### Overview

Boston Scientific Corporation is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties, including interventional cardiology, peripheral interventions, vascular surgery, electrophysiology, neurovascular intervention, oncology, endoscopy, urology, gynecology and neuromodulation. Our mission is to improve the quality of patient care and the productivity of health care delivery through the development and advocacy of less-invasive medical devices and procedures. This mission is accomplished through the continuing refinement of existing products and procedures and the investigation and development of new technologies that can reduce risk, trauma, cost, procedure time and the need for aftercare. Our approach to innovation combines internally developed products and technologies with those we obtain externally through strategic acquisitions and alliances.

## **Results of Operations**

## Financial Summary

## Three Months Ended September 30, 2005

Our net sales for the third quarter of 2005 increased to \$1,511 million from \$1,482 million for the third quarter of 2004, an increase of two percent. Excluding the favorable impact of \$8 million of foreign currency fluctuations, our net sales increased one percent. Our reported net loss for the third quarter was \$269 million, or \$0.33 per diluted share, as compared to net income of \$258 million, or \$0.30 per diluted share, for the third quarter of 2004. Our reported results for the third quarter of 2005 included charges (after-tax) of \$616 million, or \$0.75 per share, which primarily consisted of \$598 million in charges related to a litigation settlement with Medinol Ltd. and \$18 million of asset write-downs and employee-related costs that resulted from certain business optimization initiatives. Our reported results for the third quarter of 2004 included charges (after-tax) of \$146 million, or \$0.17 per share, which consisted of a \$75 million provision for a civil settlement with the U.S. Department of Justice and a \$71 million enhancement to our 401(k) Retirement Savings Plan.

Our net sales for the first nine months of 2005 increased to \$4,743 million from \$4,024 million for the same period in the prior year, an increase of 18 percent. Excluding the favorable impact of \$60 million of foreign currency fluctuations, our net sales increased 16 percent. Our reported net income for the first nine months of 2005 was \$294 million, or \$0.35 per diluted share, as compared to \$765 million, or \$0.89 per diluted share, for the same period in the prior year. Our reported results for the first nine months of 2005 included charges (after-tax) of \$888 million, or \$1.06 per share, which consisted of charges related to: a litigation settlement with Medinol; purchased research and development primarily attributable to our recent acquisitions; expenses related to certain retirement benefits; costs that resulted from certain business optimization initiatives; and a tax adjustment associated with a technical correction made to the American Jobs Creation Act. Our reported results for the first nine months of 2004 included charges (after-tax) of \$210 million, or \$0.24 per share, which consisted of: a provision for a civil settlement with the U.S. Department of Justice; an enhancement to our 401(k) Plan; and purchased research and development.

## **Net Sales**

The following tables provide our net sales by region and the relative change on an as reported and constant currency basis:

	Three Months Ended September 30,				Change		
(in millions)	2		2004		As Reported Currency Basis	Constant Currency Basis	
United States	\$	926	\$	979	(5%)	(5%)	
Europe		274		236	16%	17%	
Japan		140		144	(3%)	(1%)	
Inter-Continental		171		123	39%	30%	
International		585		503	16%	15%	
Worldwide	\$	1,511	\$	1,482	2%	1%	
		Nine Mor Septen			Chang	ge	
					As Reported	Constant	
(in millions)		2005		2004	Currency Basis	Currency Basis	
United States	\$	2,924	\$	2,499	17%	17%	
Europe		871		707	23%	20%	
Japan		440		456	(4%)	(5%)	
Inter-Continental		508		362	40%	32%	
International		1,819		1,525	19%	15%	
Worldwide	\$	4,743	\$	4,024	18%	16%	

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Our international operating regions and divisions are managed on a constant currency basis, while market risk from changes in currency exchange rates is managed at the corporate level and is reflected in operating results.

## **U.S. Net Sales**

During the third quarter of 2005, our U.S. net sales decreased by \$53 million, or five percent, as compared to the third quarter of 2004. The decrease primarily related to a \$98 million decrease in sales of our TAXUS® Express<sup>2TM</sup> paclitaxel-eluting coronary stent system to \$404 million for the third quarter of 2005 from \$502 million for the same period in the prior year due principally to competitive pressures. Growth in each of our other U.S. divisions partially offset this decrease, including increased net sales of \$24 million from our Endosurgery divisions and \$15 million from our Neuromodulation division. We established the Neuromodulation division following our June 2004 acquisition of Advanced Bionics Corporation.

During the first nine months of 2005, our U.S. net sales increased by \$425 million, or 17 percent, as compared to the same period in the prior year. The increase primarily related to \$1,365 million in sales of our TAXUS stent system for the first nine months of 2005 as compared to \$1,068 million for the same period in the prior year. We launched our TAXUS stent system in the U.S. late in the first quarter of 2004. The remainder of the increase in our U.S. net sales primarily related to sales growth of \$61 million from our Endosurgery divisions and \$58 million from our Neuromodulation division.

### International Net Sales

During the third quarter of 2005, our international net sales increased by \$82 million, or 16 percent, as compared to the third quarter of 2004. Excluding the effects of foreign currency fluctuations, international net sales increased \$74 million, or 15 percent. The increase primarily related to \$197 million in sales of the TAXUS stent system in our Europe and Inter-Continental markets for the third quarter of 2005 as compared to \$138 million for the third quarter of 2004. As of September 30, 2005, we estimate that physicians in our Europe and Inter-Continental markets have converted approximately 46 percent of the stents they use in interventional procedures from bare-metal stents to drug-eluting stents, as compared to approximately 32 percent at the end of the third quarter of 2004. In our Europe and Inter-Continental markets, conversion rates have been more gradual than in the U.S. primarily due to the timing of local reimbursement and funding levels. The remainder of the increase in our international net sales was primarily due to incremental growth of \$16 million from our Endosurgery divisions.

During the first nine months of 2005, our international net sales increased by \$294 million, or 19 percent, as compared to the same period in the prior year. Excluding the effects of foreign currency fluctuations, international net sales increased \$234 million, or 15 percent. The increase primarily related to \$585 million in sales of the TAXUS stent system in our Europe and Inter-Continental markets for the first nine months of 2005 as compared to \$385 million for the same period in the prior year. The remainder of the increase in international net sales was primarily due to incremental growth of \$50 million from our Endosurgery divisions.

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The increase in international net sales was slightly reduced by the decline in our Japan net sales. We have experienced declining coronary stent sales in Japan since a competitor launched its drug-eluting stent in this market late in the second quarter of 2004. Due to the timing of regulatory approval for our TAXUS stent system and government-mandated pricing reductions for other products, we do not expect revenue growth in our Japan business until we launch our drug-eluting stent in Japan, which we expect to occur in 2007.

The following tables provide our net sales by division and the relative change on an as reported and constant currency basis:

	Three Months Ended September 30,					Change		
(in millions)		2005		2004	As Reported Currency Basis	Constant Currency Basis		
Cardiovascular	\$	1,068	\$	1,107	(4%)	(4%)		
Electrophysiology		32		32	0%	0%		
Neurovascular		67		60	12%	12%		
Cardiovascular		1,167		1,199	(3%)	(3%)		
Oncology		52		46	13%	15%		
Endoscopy		172		157	10%	9%		
Urology/Gynecology		85		66	29%	28%		
Endosurgery		309		269	15%	15%		
Neuromodulation		35		14	150%	155%		
Worldwide	\$	1,511	\$	1,482	2%	1%		
	Nine Months Ended September 30, Cha		Chan	ge				
(in millions)		2005		2004	As Reported Currency Basis	Constant Currency Basis		
Cardiovascular	\$	3,428	\$	2,922	17%	16%		
Electrophysiology		97		95	2%	1%		
Neurovascular		206		186	11%	8%		
Cardiovascular		3,731		3,203	16%	15%		
Oncology		154		137	12%	11%		
Endoscopy		519		474	9%	8%		
Urology/Gynecology		238		189	26% _	<u>25</u> %		
Endosurgery		911		800	14%	13%		
Neuromodulation		101		21	381%	376%		
Worldwide	\$	4,743	\$	4,024	18%	16%		

## **Gross Profit**

The following table provides a summary of our gross profit:

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		Three Mont Septemb		ed			onths End	ed
_	2	2005		2004	2	005	,	2004
(in millions)	\$	% of Net Sales	\$	% of Net Sales	\$	% of Net Sales		% of Net Sales

1,173

79.1

3,699

78.0

3,060

76.0

77.3

1,168

During the third quarter of 2005, our gross profit, as a percentage of net sales, decreased by 1.8 percentage points as compared to the third quarter of 2004. Our gross profit for the third quarter of 2005 was reduced as a percentage of net sales by 0.9 percentage points due to shifts in our sales mix from higher margin products, primarily as a result of decreased sales of our TAXUS stent systems in the U.S. In addition, our gross profit for the third quarter of 2005 was reduced as a percentage of net sales by 0.7 percentage points due to period expenses, including manufacturing start-up costs primarily associated with our next-generation drug-eluting stent product, the TAXUS Liberté<sup>TM</sup> coronary stent system.

During the first nine months of 2005, our gross profit, as a percentage of net sales, increased by 2.0 percentage points as compared to the same period in the prior year. Shifts in our product sales mix toward higher margin products, primarily drug-eluting coronary stent systems in the U.S., increased our gross profit as a percentage of net sales by approximately 0.8 percentage points. Our gross profit during the first nine months of 2005 was favorably impacted by 1.4 percentage points due to \$57 million in inventory write-downs in 2004, including a \$43 million write-down attributable to our recalls of certain coronary stent systems and a \$14 million write-down attributable to our first quarter write-down of TAXUS stent system inventory due to shelf-life dating. Our gross profit for the first nine months of 2005 was reduced as a percentage of net sales by 0.9 percentage points due to period expenses, including manufacturing start-up costs primarily associated with our next-generation drug-eluting stent product, the TAXUS Liberté stent system. The remaining fluctuation in gross profit as a percentage of net sales primarily related to the favorable impact of changes in foreign exchange rates and related hedging activities.

## **Operating Expenses**

Gross profit

The following is a summary of certain operating expenses:

	Three Months Ended September 30,		Î	Nine Mont Septemb				
_	200	)5	200	04	200	05	200	)4
(in millions)	\$	% of Net Sales	\$	% of Net Sales	\$	% of Net Sales	\$	% of Net Sales
Selling, general and administrative								
expenses	444	29.4	504	34.0	1,346	28.4	1,227	30.5
Research and development expenses	181	12.0	145	9.8	506	10.7	411	10.2
Royalty expense	52	3.4	57	3.8	174	3.7	131	3.3
Amortization expense	47	3.1	34	2.3	114	2.4	82	2.0

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## Selling, General and Administrative (SG&A) Expenses

During the third quarter of 2005, our SG&A expenses decreased by \$60 million, or 12 percent, as compared to the third quarter of 2004. As a percentage of our net sales, SG&A expenses decreased to 29.4 percent for the third quarter of 2005 from 34.0 percent for the third quarter of 2004. The decrease in our SG&A expenses primarily related to the third quarter 2004 charge of \$110 million associated with an enhancement to our 401(k) Plan. The decrease is partially offset by approximately \$16 million due to increased headcount and higher compensation expense in the third quarter of 2005 mainly attributable to the expansion of sales forces within our Interventional Cardiology and Endosurgery divisions and costs related to market development initiatives, and approximately \$11 million in employee-related costs primarily as a result of optimization initiatives within our Human Resources function. In addition, our SG&A expenses for the third quarter of 2005 included approximately \$15 million in incremental operating expenses associated with our 2004 and 2005 acquisitions, primarily Advanced Bionics.

During the first nine months of 2005, our SG&A expenses increased by \$119 million, or 10 percent, as compared to the same period in the prior year. The increase in our SG&A expenses primarily related to: approximately \$90 million in increased headcount and higher compensation expense mainly attributable to the expansion of sales forces within our Interventional Cardiology and Endosurgery divisions and costs related to market development initiatives; \$17 million in costs related to certain retirement benefits; approximately \$11 million in employee-related costs primarily as a result of optimization initiatives within our Human Resources function; and approximately \$14 million in increased expense due to foreign currency fluctuations. In addition, our SG&A expenses for the first nine months of 2005 included approximately \$56 million in incremental operating expenses associated with our 2004 and 2005 acquisitions, primarily Advanced Bionics. In 2004, our SG&A expenses included a charge of \$110 million attributable to an enhancement to our 401(k) Plan. The remaining change in our SG&A expenses for the first nine months of 2005 as compared to the same period in the prior year was due to incremental increases that were individually immaterial. As a percentage of our net sales, SG&A expenses decreased to 28.4 percent for the first nine months of 2005 from 30.5 percent for the same period in the prior year due to the significant increase in our net sales.

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## Research and Development Expenses

Our research and development expenses reflect ongoing spending to enhance our clinical and regulatory infrastructure and provide additional funding for our research and development on next-generation and novel technology offerings across multiple programs and divisions. For the third quarter of 2005, our research and development expenses increased by \$36 million, or 25 percent, as compared to the third quarter of 2004. As a percentage of our net sales, research and development expenses increased to 12.0 percent for the third quarter of 2005 from 9.8 percent for the third quarter of 2004. This increase primarily related to \$17 million in incremental research and development expenses attributable to our 2004 and 2005 acquisitions, primarily Advanced Bionics and TriVascular, Inc. In addition, we increased spending on internal research and development projects within our Endosurgery divisions by \$8 million, including increased spending on our Endovations<sup>TM</sup> Endoscopy System.

For the first nine months of 2005, our research and development expenses increased by \$95 million, or 23 percent, as compared to the same period in the prior year. As a percentage of our net sales, research and development expenses increased to 10.7 percent for the first nine months of 2005 from 10.2 percent for the same period in the prior year. This increase primarily related to \$51 million in incremental research and development expenses attributable to our 2004 and 2005 acquisitions, primarily Advanced Bionics and TriVascular. In addition, we increased spending on our internal research and development projects within our Endosurgery divisions by \$20 million, including increased spending on our Endovations Endoscopy System.

## **Royalty Expense**

For the third quarter of 2005, our royalty expense decreased by \$5 million, or nine percent, as compared to the third quarter of 2004. As a percentage of our net sales, royalty expense decreased to 3.4 percent for the third quarter of 2005 from 3.8 percent for the same period in the prior year. The decrease in our royalty expense related to decreased net sales of royalty-bearing products for the third quarter of 2005, primarily sales of our TAXUS stent system. Royalty expense attributable to sales of our TAXUS stent system decreased by \$5 million to \$39 million for the third quarter of 2005 as compared to the third quarter of 2004.

For the first nine months of 2005, our royalty expense increased by \$43 million, or 33 percent, as compared to the same period in the prior year. As a percentage of our net sales, royalty expense increased to 3.7 percent for the first nine months of 2005 as compared to 3.3 percent for the same period in the prior year. The increase in our royalty expense related to sales growth of royalty-bearing products during the first nine months of 2005, primarily sales of our TAXUS stent system. Royalty expense attributable to sales of our TAXUS stent system increased by \$39 million to \$134 million for the first nine months of 2005 as compared to the same period in the prior year.

## **Amortization Expense**

For the third quarter of 2005, our amortization expense increased by \$13 million, or 38 percent, as compared to the third quarter of 2004. The increase in our amortization expense was primarily due to a \$10 million write-off of intangible assets related to our Enteryx® Liquid Polymer Technology (Enteryx), a discontinued technology platform obtained as a part of our Enteric Medical Technologies, Inc. (EMT) acquisition. The write-off resulted from our decision during the third quarter of 2005 to cease selling the Enteryx product.

For the first nine months of 2005, our amortization expense increased by \$32 million, or 39 percent, as compared to the same period in the prior year. The increase in our amortization expense primarily related to a \$10 million write-off of intangible assets related to Enteryx, a discontinued technology platform obtained as a part of our EMT acquisition. In addition, the increase in our amortization expense related to the amortization of intangible assets from our 2004 and 2005 acquisitions, primarily Advanced Bionics.

## **Interest Expense**

For the first nine months of 2005, our interest expense increased to \$58 million as compared to \$44 million for the same period in the prior year. The increase in our interest expense primarily related to an increase in average market interest rates, as well as an increase in our average debt levels.

## **Tax Rate**

The following table provides a summary of our reported tax rate:

		Three Months Ended September 30,		
	2005	2004	(Decrease)/Increase	
Reported tax rate	24%	26%	(2%)	
Impact of certain charges*	0%	(2%)	2%	
		nths Ended aber 30,	Percentage Point	
	2005	2004	Increase/(Decrease)	
Reported tax rate	35%	26%	9%	
Impact of certain charges*	(11%)	(2%)	(9%)	

<sup>\*</sup>These charges are taxed at different rates than our effective tax rate.

For the third quarter of 2005, our reported tax rate decreased as compared to the same period in the prior year primarily due to the net impact of certain charges that are taxed at different rates than our effective tax rate. These charges included: certain litigation-related charges; an enhancement to our 401(k) Plan; and asset write-downs and employee-related costs that resulted from certain business optimization initiatives.

For the first nine months of 2005, our reported tax rate increased as compared to the same period in the prior year primarily due to the net impact of certain charges that are taxed at different rates than our effective tax rate. These charges included: certain litigation-related charges; purchased research and development; an enhancement to our 401(k) Plan; costs related to certain retirement benefits; asset write-downs and employee-related costs that resulted from certain business optimization initiatives; and a benefit for a tax adjustment associated with a technical correction made to the American Jobs Creation Act.

Management currently estimates that our effective tax rate, excluding certain charges, will approximate 24 percent during the remainder of 2005. However, our effective tax rate could be impacted positively or negatively by geographic changes in the manufacturing of our products or by our business acquisitions.

## **Business Combinations and Purchased Research and Development**

During 2005, we acquired the following entities:

- Advanced Stent Technologies, Inc. (AST) a developer of stent delivery systems that are designed to
  address coronary artery disease in bifurcated vessels. In conjunction with our March 2005 acquisition of
  AST, we paid approximately \$120 million in shares of our common stock plus future consideration that is
  contingent upon AST achieving certain regulatory and performance-related milestones.
- TriVascular a developer of medical devices and procedures used for treating abdominal aortic aneurysms
  (AAA). In conjunction with our April 2005 acquisition of TriVascular, we paid approximately \$65 million
  in addition to our previous investments and notes issued of approximately \$45 million in the aggregate,
  plus future consideration that is contingent upon TriVascular achieving certain regulatory and performancerelated milestones.
- CryoVascular Systems, Inc. a developer and manufacturer of a proprietary angioplasty device to treat
  atherosclerotic disease of the legs and other peripheral arteries, which we previously distributed. In
  conjunction with our April 2005 acquisition of CryoVascular, we paid approximately \$50 million in
  addition to our previous investments of approximately \$10 million, plus future consideration that is
  contingent upon CryoVascular achieving certain performance-related milestones.
- Rubicon Medical Corporation a developer of embolic protection filters for use in interventional
  cardiovascular procedures. In conjunction with our April 2005 acquisition of Rubicon, we paid
  approximately \$70 million in addition to our previous investments of approximately \$20 million, plus
  future consideration that is contingent upon Rubicon achieving certain regulatory and performance-related
  milestones.

We are currently considering the exercise of our option to acquire EndoTex Interventional Systems, Inc. (EndoTex), a developer of stents used in the treatment of stenotic lesions in the carotid arteries. In conjunction with the acquisition of EndoTex, we would pay approximately \$100 million in addition to our previous investments and notes issued of approximately \$35 million, plus future consideration that is contingent upon EndoTex achieving certain performance-related milestones.

Our 2005 purchased research and development consisted of: \$130 million relating to our acquisition of TriVascular; \$73 million relating to our acquisition of AST; \$45 million relating to our acquisition of Rubicon; and \$3 million relating to our acquisition of CryoVascular. In addition, we recorded \$25 million of purchased research and development in conjunction with obtaining distribution rights for new brain monitoring technology that Aspect Medical Systems, one of our strategic partners, is currently developing. This technology is designed to aid the diagnosis and treatment of depression and other neurological conditions.

For the in-process projects we acquired in connection with our 2005 acquisitions, we used risk-adjusted discount rates that ranged from 18 percent to 27 percent to discount the projected cash flows. We believe that the estimated purchased research and development amounts so determined represent the fair value at the date of acquisition and do not exceed the amount a third party would pay for the projects. We valued and accounted for the purchased research and development from our 2005 acquisitions in accordance with our policy described in the "Critical Accounting Policies" section of our 2004 Annual Report on Form 10K.

The most significant in-process projects acquired in conjunction with our 2005 acquisitions included TriVascular's AAA stent-graft and AST's Petal<sup>TM</sup> bifurcation stent, which collectively represented 73 percent of our 2005 acquired in-process projects. TriVascular's AAA stent-graft design reduces the size of the stent-graft by replacing much of the metal stent assembly with a polymer that is injected into channels within the stent-graft during the procedure. We estimate the cost to complete the AAA stent-graft to be approximately \$100 million. As of the date we acquired TriVascular, we expected the AAA stent-graft to be commercially available on a worldwide basis in approximately 4 years.

AST's Petal bifurcation stent is designed to expand into the side vessel when a single vessel branches into two vessels, permitting blood to flow into both branches of the bifurcation and providing support at the junction. We estimate the cost to complete the Petal bifurcation stent to be between \$100 million and \$125 million. As of the date we acquired AST, we expected the Petal bifurcation stent to be commercially available on a worldwide basis within 6 years in a drug-eluting configuration.

The most significant in-process projects acquired in connection with our 2004 acquisitions included Advanced Bionics' bion® microstimulator and drug delivery pump. The bion microstimulator is an implantable neurostimulation device designed to treat a variety of neurological conditions, including migraine headaches and urge

incontinence. We continue to pursue the development of the bion microstimulator and believe we have a reasonable chance of completing this project. The cost to complete the bion microstimulator is estimated to be between \$35 million and \$45 million. We expect that the bion microstimulator will be commercially available within three years.

The drug delivery pump is an implanted programmable device designed to treat chronic pain. The cost to complete the drug delivery pump is estimated to be between \$30 million and \$40 million. We continue to assess our opportunities for the drug delivery pump, which may result in a delay in the timing of regulatory approval.

In connection with our 2002 acquisitions, we acquired several in-process projects, including Smart Therapeutics, Inc.'s (Smart) atherosclerosis stent. The atherosclerosis stent is a self-expanding nitinol stent designed to treat narrowing of the arteries around the brain. During 2005, we completed the atherosclerosis stent in-process project and received Humanitarian Device Exemption approval to begin selling this technology on a limited basis. The total cost for us to complete the project was approximately \$10 million.

In connection with our 2001 acquisitions, we acquired several significant in-process projects, including Interventional Technologies, Inc.'s (IVT) next-generation Cutting Balloon®. The Cutting Balloon is a novel balloon angioplasty device with mounted scalpels that relieve stress in the artery, reducing the force necessary to expand the vessel. This contributes to less inadvertent arterial trauma and injury as compared to standard balloon angioplasty. During 2005, we completed the Cutting Balloon in-process project and received FDA approval for this technology. The total cost for us to complete the project was approximately \$7 million.

## Litigation-Related Charges

In the third quarter of 2005, we recorded a \$780 million pre-tax charge associated with the Medinol litigation settlement. On September 21, 2005, we reached a settlement with Medinol resolving certain contract and patent infringement litigation. In conjunction with the settlement agreement, we paid \$750 million in cash and cancelled our equity investment in Medinol. In the third quarter of 2004, we recorded a \$75 million provision for a civil settlement with the U.S. Department of Justice.

## Outlook

During the first nine months of 2005, we increased net sales by 18 percent as compared to the same period in the prior year. We continued to invest in our sales force and research and development pipeline during the first nine months of 2005 to support our short and long-term growth initiatives, resulting in a 10 percent increase in SG&A and a 23 percent increase in research and development expenses relative to the same period in 2004. In addition, we will continue to examine our operations and research and development portfolio in order to identify cost containment measures that will align operating expenses with future revenue levels and reallocate resources to support growth initiatives.

Coronary Stents

Coronary stent revenue represented 43 percent of our consolidated net sales during the first nine months of 2005. We have experienced declines in our U.S. drug-eluting stent revenues largely as a result of competitive pressures and a slight reduction in the U.S. market size as a result of lower re-intervention rates with drug-eluting stents as compared to bare-metal stents. The unfavorable impact of these factors has been partially offset by increased worldwide conversion rates, particularly in our Europe and Inter-Continental markets.

We estimate that the worldwide coronary stent market will approximate \$5.8 billion in 2005 and \$6.0 billion in 2006. Drug-eluting stents are estimated to represent approximately 87 percent of the worldwide coronary stent market in 2005 and 90 percent in 2006. As of the third quarter of 2005, we believe that the U.S. stent market has been substantially penetrated and estimate that physicians in the U.S. have converted approximately 89 percent of the stents they use in interventional procedures from bare-metal stents to drug-eluting stents. In contrast, as of the third quarter of 2005, we estimate that physicians in our Europe and Inter-Continental markets have converted approximately 46 percent of the stents they use in interventional procedures from bare-metal stents to drug-eluting stents, which represents a significant increase as compared to approximately 32 percent at the end of the third quarter of 2004. We expect that conversion rates will continue to increase in our Europe and Inter-Continental markets. We successfully launched our next-generation drug-eluting stent, the TAXUS Liberté stent system, in certain Inter-Continental markets during the first quarter of 2005 and in Europe during the third quarter of 2005. We believe our TAXUS Liberté stent system represents a potential significant driver of future growth in these markets. Further, subject to regulatory approval we expect to launch our TAXUS Express<sup>2</sup> stent system in Japan during the first half of 2007, where we estimate the size of the market in 2005 to approximate \$500 million.

Historically, the worldwide coronary stent market has been dynamic and highly competitive with significant market share volatility. In addition, in the ordinary course of our business, we conduct and participate in numerous clinical trials with a variety of study designs, patient populations and trial endpoints. Unfavorable or inconsistent clinical data from existing or future clinical trials conducted by us, by our competitors or by third parties, or the market's perception of this clinical data, may adversely impact our position in and share of the drug-eluting stent market and may contribute to increased volatility in the market.

However, we believe that we can maintain a leadership position within the drug-eluting stent markets in which we compete for a variety of reasons, including:

- the positive and consistent results of our TAXUS clinical trials;
- the performance benefits of our current technology;
- the strength of our pipeline of drug-eluting stent products and the planned launch sequence of these products;

- our overall market leadership in interventional medicine and our sizeable interventional cardiology sales force; and
- our significant investments in our sales, clinical, marketing and manufacturing capabilities.

However, a material decline in our drug-eluting stent revenue would have a significant adverse impact on our future operating results. The most significant variables that may impact the size of the drug-eluting coronary stent market and our position within this market include:

- unexpected variations in clinical results or product performance of our and our competitions' products;
- the timing of new competitive launches;
- the average selling prices of drug-eluting stent systems;
- delayed or limited regulatory approvals and reimbursement policies;
- litigation related to intellectual property;
- continued physician confidence in our technology;
- the average number of stents used per procedure;
- expansion of indications for use;
- the international adoption rate of drug-eluting stent technology; and
- the level of supply of our drug-eluting stent system and competitive stent systems.

Our drug-eluting stent system is currently one of only two drug-eluting products in the U.S. market. Our share of the drug-eluting stent market as well as unit prices may be adversely impacted as additional significant competitors enter the drug-eluting stent market, which has begun during the third quarter of 2005 internationally and is expected to occur during 2007 in the U.S. In 2004, Johnson & Johnson announced its intention to acquire Guidant Corporation (Guidant). Johnson & Johnson and Guidant are two of our primary competitors in the coronary stent market and this acquisition, whether or not consummated, may increase volatility and uncertainty within the coronary stent market.

The manufacture of our TAXUS stent system involves the integration of multiple technologies, critical components, raw materials and complex processes. Significant favorable or unfavorable changes in forecasted demand as well as disruptions associated with our TAXUS stent manufacturing process may impact our inventory levels. Variability in expected demand or the timing of the launch of next-generation products may result in excess or expired inventory positions and future inventory charges.

## Intellectual Property Litigation

There continues to be significant intellectual property litigation in the coronary stent market. We are currently involved in a number of legal proceedings with our competitors, including Johnson & Johnson and Medtronic, Inc. There can be no assurance that an adverse outcome in one or more of these proceedings would not impact our ability to meet our objectives in the market. See the Legal Matters section within Management's Discussion and Analysis and Note H to our unaudited condensed

consolidated financial statements contained in this Quarterly Report and our 2004 Annual Report filed on Form 10-K for a description of these legal proceedings.

## Regulatory Compliance

The trend in countries around the world, including the U.S. and Japan, toward more stringent regulatory requirements for product clearance, changing reimbursement models and more rigorous inspection and enforcement activities has generally caused or may cause medical device manufacturers like us to experience more uncertainty, delay, risk and expense. We have recently received several warning letters from the FDA in reference to our global quality-control systems that we are working with the FDA to resolve. Further, during 2004, we received a warning letter from the FDA associated with our auditory product line that we are working to resolve. There can be no assurances regarding the length of time it will take to resolve these issues, and any such resolution may require the dedication of significant internal and external resources. In addition, we are required to renew regulatory approvals in certain international jurisdictions, which may require additional testing and documentation. A decision not to dedicate sufficient resources, or the failure to timely renew these approvals, may limit our ability to market our full line of existing products within these jurisdictions.

### Innovation

Our approach to innovation combines internally developed products and technologies with those we obtain externally through our strategic acquisitions and alliances. Our research and development program is largely focused on the development of next-generation and novel technology offerings across multiple programs and divisions. We expect to continue to invest aggressively in our drug-eluting stent program to achieve sustained worldwide market leadership positions. We successfully launched our next-generation drug-eluting stent product, the TAXUS Liberté stent system, in certain Inter-Continental markets during the first quarter of 2005 and in Europe during the third quarter of 2005. We expect to launch our TAXUS Liberté stent system in the U.S. during the second half of 2006, subject to regulatory approval. Further, we anticipate continuing our increased focus and spending on areas outside of drug-eluting stent technology. We believe our focus will be primarily on technologies in which we have already made significant investments, including neuromodulation, endoscopic systems, carotid stenting, vascular sealing, endovascular aortic repair, cardiac rhythm management, and bifurcation stenting, but may also extend into other medical device opportunities. However, given their early stage of development, there can be no assurance that these technologies will achieve technological feasibility, obtain regulatory approval or gain market acceptance. A delay in the development or approval of these technologies may adversely impact our future growth. Our agreement to distribute certain guidewire products will expire during the first quarter of 2006. We are in the process of procuring a replacement product.

Our acquisitions and alliances are intended to expand further our ability to offer our customers effective, quality medical devices that satisfy their interventional needs. Management believes it has developed a sound plan to integrate acquired businesses. However, our failure to integrate these businesses successfully could impair our ability to realize the strategic and financial objectives of these transactions. Potential future

acquisitions, including companies with whom we currently have strategic alliances or options to purchase, may be dilutive to our earnings and may require additional financing, depending on their size and nature. Further, in connection with these acquisitions and other strategic alliances, we have acquired numerous in-process research and development projects. As we continue to undertake strategic initiatives, it is reasonable to assume that we will acquire additional in-process research and development projects.

In addition, we have entered a significant number of strategic alliances with privately held and publicly traded companies. Many of these alliances involve equity investments and often give us the option to acquire the other company or assets of the other company in the future. We enter these strategic alliances to broaden our product technology portfolio and to strengthen and expand our reach into existing and new markets. The success of these alliances is an important element of our growth strategy and we will continue to seek market opportunities and growth through investments in strategic alliances and acquisitions. However, the full benefit of these alliances is often dependent on the strength of the other companies' underlying technology and ability to execute. An inability to achieve regulatory approvals and launch competitive product offerings, or litigation related to these technologies, among other factors, may prevent us from realizing the benefit of these alliances.

### International Markets

Further, international markets are also being affected by economic pressure to contain reimbursement levels and healthcare costs. Our profitability from our international operations may be limited by risks and uncertainties related to economic conditions in these regions, foreign currency fluctuations, regulatory and reimbursement approvals, competitive offerings, infrastructure development, rights to intellectual property and our ability to implement our overall business strategy. Any significant changes in the competitive, political, regulatory, reimbursement or economic environment where we conduct international operations may have a material impact on our revenues and profits.

These factors may impact the rate at which we can grow. However, management believes that we are poised to take advantage of opportunities that exist in the markets we serve.

## Liquidity and Capital Resources

The following table provides a summary of key performance indicators that we use to assess our liquidity:

Nine Months Ended

Nine Months Ended

	Time World Ended					
	September 30,					
(in millions)		005	2004			
Cash provided by operating activities	\$	393 \$	1,147			
Cash used for investing activities		459	1,679			
Cash (used for)/provided by financing activities		(478)	967			
EBITDA		721	1,260			

Management uses EBITDA<sup>1</sup> to assess operating performance and believes it may assist users of our financial statements in analyzing the underlying trends in our business over time. Users of our financial statements should consider this non-GAAP financial information in addition to, not as a substitute for, or as superior to, financial information prepared in accordance with GAAP. Our EBITDA included pre-tax charges of \$1,101 million for the first nine months of 2005 and \$249 million for the same period in the prior year.

## **Operating Activities**

The decrease in cash generated by our operating activities was primarily related to the decrease in EBITDA, the level of purchased research and development in 2005 and changes in operating assets and liabilities during 2005. The decrease in EBITDA reflects our third quarter 2005 settlement with Medinol. This decrease was offset by increased sales of our TAXUS stent system during the first nine months of 2005. We invested a portion of the cash generated from our TAXUS stent system in our sales, clinical and manufacturing capabilities and in research and development projects.

Significant cash flow effects from operating assets and liabilities in the first nine months of 2005 included uses in cash flows of approximately \$36 million attributable to trade accounts receivable; \$165 million attributable to accounts payable and accrued expenses; \$84 million attributable to inventories; and approximately \$106 million attributable to taxes payable and other liabilities. The increase in trade accounts receivable primarily related to our sales growth during the first nine months of 2005. The decrease in accounts payable and accrued expenses primarily related to our \$74 million settlement payment to the Department of Justice and our one-time \$110 million 401(k) contribution that were both made during June of 2005. The increase in inventories primarily related

<sup>1</sup> The following table represents a reconciliation between EBITDA and net income	<sup>1</sup> The following t	table represents a	a reconciliation between	ERITDA and net income
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	September 30,					
(in millions)	2005		2004			
EBITDA	\$ 72	1 \$	1,260			
Interest income	20	5	12			
Depreciation and amortization	(230	5)	(193)			
Interest expense	(53	3)	(44)			
Income taxes	(159	<u>)</u>	(270)			
Net income	\$ 294	<u>\$</u>	765			

to our accumulation of inventory to fulfill worldwide demand for our TAXUS stent system and our Neuromodulation product offerings. The decrease in taxes payable and other liabilities primarily related to tax payments made during 2005 including those associated with the American Jobs Creation Act and the expected tax benefit related to the settlement agreement with Medinol, partially offset by the increase in taxes payable associated with our 2005 earnings growth.

During the first quarter of 2005, we repatriated approximately \$1,046 million in extraordinary dividends as defined in the American Jobs Creation Act from our non-U.S. operations.

## **Investing Activities**

We made capital expenditures of \$267 million during the first nine months of 2005 as compared to \$201 million for the same period in the prior year. The increase primarily related to capital spending to enhance our manufacturing and distribution capabilities. We expect to incur capital expenditures of approximately \$100 million during the remainder of 2005, which includes additional investments in our facility network and research and development capabilities.

Our investing activities during the first nine months of 2005 included \$178 million of net payments for our acquisitions of TriVascular, CryoVascular and Rubicon; \$25 million of acquisition-related payments primarily associated with Catheter Innovations, Inc.; and \$178 million of net payments for strategic alliances with both privately held and publicly traded entities.

## **Financing Activities**

Our cash flow from financing activities reflects issuances and repayments of debt; payments for share repurchases; and proceeds from stock issuances related to our equity incentive programs.

### Debt

The following table provides a summary at September 30, 2005 and December 31, 2004 of our net debt:

(in millions)	September           30,         December           2005         2004				
Short-term debt Long-term debt	\$	84 2,430	\$	1,228 1,139	
Gross debt	<del></del>	2,514		2,367	
Less: cash, cash equivalents and marketable securities		917		1,640	
Net debt	<u>\$</u>	1,597	\$	727	

During the first nine months of 2005, we received net borrowing proceeds of \$179 million. These proceeds are primarily from approximately \$1,095 million in net

commercial paper issuances, offset by a repayment of our \$500 million 6.625 percent senior notes that matured in March 2005 and our 45 billion Japanese yen (approximately \$400 million) credit facility borrowings that matured in September 2005. The increase in our net debt during the first nine months of 2005 was primarily due to funding the litigation settlement with Medinol, share repurchases, acquisitions and strategic alliances.

During the first nine months of 2005, we refinanced our revolving credit facilities to extend the maturity of one credit facility and to reduce total borrowing capacity by \$165 million. At September 30, 2005, our revolving credit facilities totaled approximately \$2,020 million and consisted of a \$1,500 million credit facility that terminates in May 2009; a \$500 million credit facility that terminates in May 2010 and contains an option to increase the facility size by an additional \$500 million in the future; and a \$20 million uncommitted credit facility that terminates in May 2006. Our use of these borrowings is unrestricted and the borrowings are unsecured. Our revolving credit facilities provide us with borrowing capacity and support our commercial paper program. We had \$1,375 million of commercial paper outstanding at September 30, 2005 at a weighted average interest rate of 3.73 percent and \$280 million outstanding at December 31, 2004 at a weighted average interest rate of 2.44 percent.

In addition, we decreased our credit and security facility that is secured by our U.S. trade receivables from \$400 million to \$100 million, effective April 30, 2005. This credit and security facility terminates in August 2006. As of September 30, 2005 and December 31, 2004, there were no outstanding borrowings under this credit and security facility.

As of September 30, 2005, we had the ability and intent to refinance a portion of our short-term debt on a long-term basis through our revolving credit facilities and expected that a minimum of \$1,300 million of our short-term obligations, consisting of commercial paper, would remain outstanding beyond a twelve-month period. Accordingly, at September 30, 2005, we classified \$1,300 million of our short-term borrowings as long-term borrowings. No such reclassification was made at December 31, 2004.

Given favorable market conditions, we are considering the issuance of up to \$750 million in long-term debt securities during the fourth quarter of 2005 under a public registration statement that we previously filed with the SEC. As of the end of the third quarter of 2005, we have \$1,000 million available under this public registration statement to issue various debt and equity securities. In the event that we issue long-term debt securities, we anticipate filing a new public registration statement with the SEC to increase the amount of debt and equity securities we can issue from the \$250 million remaining under the existing registration statement to a total of \$1,500 million to maintain our ready access to the public capital markets.

### Equity

During the first nine months of 2005, we repurchased 25 million shares of our common stock at an aggregate cost of \$734 million under our share repurchase program authorized by our Board of Directors. At the end of the third quarter of 2005, 37 million shares of our common stock remain are authorized for repurchase under our share

repurchase program. Repurchased shares are available for reissuance under our equity incentive plans and for general corporate purposes, including acquisitions and strategic alliances.

During the first nine months of 2005, we received proceeds of \$77 million in connection with the issuance of our shares pursuant to stock option and employee stock purchase plans as compared to \$208 million for the same period in the prior year.

## **Contractual Obligations and Commitments**

Certain of our business combinations involve the payment of contingent consideration. Certain earn-out payments are determined based on the acquired company's achievement of certain regulatory and/or performance-related milestones and, consequently, we cannot currently determine the total payments attributable to these business combinations. However, we have developed an estimate of the maximum potential contingent consideration for each of our acquisitions with an outstanding earn-out obligation. At September 30, 2005, the estimated maximum potential amount of future contingent consideration (undiscounted) that we could be required to make associated with our business combinations is approximately \$4.5 billion, some of which may be payable in our common stock. The regulatory and performance-related milestones that must be reached before the contingent consideration is payable will occur or will not occur in certain future periods ranging from 2005 through 2014. The estimated cumulative specified revenue level associated with these maximum future contingent payments is approximately \$10 billion.

### Legal Matters

The interventional medicine market in which we primarily participate is in large part technology driven. Physician customers, particularly in interventional cardiology, move quickly to new products and new technologies. As a result, intellectual property rights, particularly patents and trade secrets, play a significant role in product development and differentiation. However, intellectual property litigation to defend or create market advantage is inherently complex and unpredictable. Furthermore, appellate courts frequently overturn lower court patent decisions.

In addition, competing parties frequently file multiple suits to leverage patent portfolios across product lines, technologies and geographies and to balance risk and exposure between the parties. In some cases, several competitors are parties in the same proceeding, or in a series of related proceedings, or litigate multiple features of a single class of devices. These forces frequently drive settlement not only of individual cases, but also of a series of pending and potentially related and unrelated cases. In addition, although monetary and injunctive relief is typically sought, remedies and restitution are generally not determined until the conclusion of the proceedings, and are frequently modified on appeal. Accordingly, the outcomes of individual cases are difficult to time, predict or quantify and are often dependent upon the outcomes of other cases in other geographies.

Several third parties have asserted that our current and former stent systems infringe patents owned or licensed by them. Adverse outcomes in one or more of these proceedings could limit our ability to sell certain stent products in certain jurisdictions, or reduce our operating margin on the sale of these products. In addition, damage awards related to historical sales could be material. We have similarly asserted that stent systems or other products sold by these third parties infringe patents owned or licensed by us.

Note H to our unaudited condensed consolidated financial statements contained in this quarterly report identifies all material developments with regard to any matters of litigation disclosed in our Form 10-K for the year ended December 31, 2004 or instituted since December 31, 2004. The developments that are disclosed below are those that we believe are the most significant.

On October 22, 1997, Cordis Corporation (Cordis), a subsidiary of Johnson & Johnson, filed a suit in the U.S. District Court for the District of Delaware for patent infringement against us and one of our subsidiaries, alleging that the importation and use of the NIR® stent infringes patents owned by Cordis. On March 24, 2005, a jury found that a single claim of one Cordis patent was valid and infringed. The jury only determined liability; any monetary damages will be determined at a later trial. We, however, have requested the judge to enter judgment in our favor as a matter of law, and intend to appeal any adverse decision. Even though it is reasonably possible that we may incur a liability associated with this case, we do not believe that a loss is probable or estimable. Therefore, we have not accrued for any losses associated with this case.

On January 13, 2003, Cordis filed suit in the U.S. District Court for the District of Delaware for patent infringement against us and one of our subsidiaries, alleging that our Express coronary stent infringes a U.S. patent owned by Cordis. On August 4, 2004, the Court granted a Cordis motion to add our Liberté<sup>TM</sup> coronary stent and two additional patents to the complaint. On June 21, 2005, a jury found that our TAXUS Express<sup>2</sup>, Express<sup>2</sup>, Express<sup>TM</sup> Biliary and Liberté<sup>TM</sup> stents infringe a Johnson & Johnson patent, and that our Liberté stent infringes a second Johnson & Johnson patent. We have requested the judge enter judgment in our favor as a matter of law, and intend to appeal any adverse decision. On July 1, 2005, a jury found that Johnson & Johnson's Cypher®, Bx Velocity®, Bx SONIC and GENESIS stents infringe one of our patents asserted in our counterclaim. The juries only determined liability; monetary damages will be determined at a later trial. Even though it is reasonably possible that we may incur a liability associated with this case, we do not believe that a loss is probable or estimable. Therefore, we have not accrued for any losses associated with this case.

On March 13, 2003, we and one of our subsidiaries filed suit in the U.S. District Court for the District of Delaware for patent infringement against Johnson & Johnson and Cordis, alleging that their Cypher drug-eluting stent infringes a patent owned by us. On July 1, 2005, a jury found that Johnson & Johnson's Cypher drug-eluting stent infringes one of our patents. The jury determined liability only; any monetary damages will be determined at a later trial. Johnson & Johnson has requested the judge enter a judgment in its favor as a matter of law.

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On May 12, 2004, we (through a subsidiary) filed suit in the District Court of The Hague in The Netherlands against two of Johnson & Johnson's Dutch subsidiaries, alleging that Cordis' Bx Velocity stent, Bx Sonic stent, Cypher stent, Cypher Select stent, Aqua T3 delivery systems for those stents, and U-Pass angioplasty balloon catheters infringe one of our European patents. On June 8, 2005, the Court found that the Johnson & Johnson products infringe our patent and granted injunctive relief. On June 23, 2005, the District Court in Assen, The Netherlands stayed enforcement of the injunction. On October 12, 2005, an appellate court reinstated the injunction.

On April 5, 2001, Medinol filed a complaint in the U.S. District Court for the Southern District of New York against us alleging breaches of contract, fraud and other claims. On April 26, 2001, Medinol amended its complaint to add claims alleging misappropriation of trade secrets in relation to our Express stent development program. Medinol sought monetary and injunctive relief, as well as an end to our right to distribute Medinol stents and to gain access to certain of our intellectual property. On September 21, 2005, the companies reached a settlement agreement which resolved most outstanding litigation. The settlement agreement called for us to pay \$750 million to Medinol, cancel our equity investment in Medinol and dictates that certain future disputes must be resolved through a defined arbitration process.

In October 1998, we recalled our NIR ON® Ranger<sup>TM</sup> with Sox<sup>TM</sup> coronary stent delivery system following reports of balloon leaks. Beginning in November 1998, the U.S. Department of Justice conducted an investigation primarily regarding: the shipment, sale and subsequent recall of the NIR ON® Ranger with Sox stent delivery system; aspects of our relationship with Medinol, the vendor of the stent; and related events. On June 24, 2005, we entered into a civil settlement with the U.S. Department of Justice. As part of the agreement, we paid \$74 million. Also pursuant to the agreement, the Department of Justice filed a complaint in the U.S. District Court for the District of Massachusetts together with a Notice of Dismissal with prejudice. No charges were brought against us or any of our employees. The settlement involves no admission of any wrongdoing by us or any of our employees. We believe we acted legally, responsibly and appropriately at all times.

## **New Accounting Standard**

During 2004, the FASB issued Statement No. 123(R), Share-Based Payment, which is a revision of Statement No. 123, Accounting for Stock-Based Compensation. Statement No. 123(R) supersedes APB Opinion No. 25, Accounting for Stock Issued to Employees and amends Statement No. 95, Statement of Cash Flows. In general, Statement No. 123(R) contains similar accounting concepts as those described in Statement No. 123. However, Statement No. 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative. Alternative phase-in methods are allowed under Statement No. 123(R), which was to be effective as of the beginning of the first interim or annual reporting period that begins after June 15, 2005. The SEC announced in the second quarter of 2005 that it would extend this phase-in period and, therefore, our effective date for implementation of Statement No. 123(R) is January 1,

2006. We are considering adopting Statement No. 123(R) using the "modified-prospective method," which is a method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement No. 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement No. 123 for all awards granted to employees prior to the effective date of Statement No. 123(R) that remain unvested on the effective date. We expect to apply the Black-Scholes valuation model in determining the fair value of share-based payments to employees, which will then be amortized on a straight-line basis.

The impact of adoption of Statement No. 123(R) cannot be quantified at this time because it will depend on the level of share-based payments granted in the future, expected volatilities and expected useful lives, among other factors, present at the grant date. However, had Statement No. 123(R) been effective in prior periods, the impact of that standard would have approximated the impact of Statement No. 123 as described in our disclosure of pro forma net (loss)/income and net (loss)/income per share in Note B to our condensed consolidated interim financial statements.

# Cautionary Statement for Purposes of the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995

Certain statements that we may make from time to time, including statements contained in this report and information incorporated by reference into this report, constitute "forward-looking statements." Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," intend" and similar words used in connection with, among other things, discussions of our financial performance, growth strategy, regulatory approvals, product development or new product launches, market position, sales efforts, intellectual property matters or acquisitions and divestitures. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. As a result, investors are cautioned not to place undue reliance on any of our forward-looking statements.

We do not intend to update these forward-looking statements even if new information becomes available or other events occur in the future. We have identified these forward-looking statements in order to take advantage of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Certain factors that could cause actual results to differ materially from those expressed in forward-looking statements are contained below.

### **Coronary Stents**

Volatility in the coronary stent market, competitive offerings and the timing of receipt of regulatory
approvals to market existing and anticipated drug-eluting stent technology and other coronary and peripheral
stent platforms;

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- Our ability to launch our TAXUS Express<sup>2</sup> stent system in Japan during the first half of 2007, and to launch
  our next-generation drug-eluting stent system, the TAXUS Liberté stent system, in the U.S. during the second
  half of 2006 and to maintain or expand our worldwide market leadership positions through reinvestment in
  our drug-eluting stent program;
- The continued availability of our TAXUS stent system in sufficient quantities and mix, our ability to prevent disruptions to our TAXUS stent system manufacturing processes and to maintain or replenish inventory levels consistent with forecasted demand around the world as we transition to next-generation stent products;
- The impact of new drug-eluting stents on the size of the coronary stent market, distribution of share within the coronary stent market in the U.S. and around the world, and average selling prices;
- The overall performance of and continued physician confidence in our and other drug-eluting stents and the results of drug-eluting stent clinical trials undertaken by us, our competitors or other third parties;
- Continued growth in the rate of physician adoption of drug-eluting stent technology in our Europe and Inter-Continental markets;
- Our ability to take advantage of our position as one of two early entrants in the U.S. drug-eluting stent market, to anticipate competitor products as they enter the market and to take advantage of opportunities that exist in the markets we serve; and
- Our ability to manage inventory levels, accounts receivable, gross margins and operating expenses relating to our TAXUS stent system and other product franchises and to react effectively to worldwide economic and political conditions.

## Litigation and Regulatory Compliance

- The effect of litigation, risk management practices including self-insurance, and compliance activities on our loss contingency, legal provision and cash flow;
- The impact of stockholder derivative and class action, patent, product liability and other litigation; and
- Any conditions imposed in resolving, or any inability to resolve, outstanding warning letters or other FDA
  matters, as well as risks generally associated with regulatory compliance, quality systems standards and
  complaint-handling.

### Innovation

• Our ability to successfully complete planned clinical trials, to obtain regulatory approvals and to develop and launch products on a timely basis within cost estimates, including the successful completion of in-process projects from purchased research and development;

- Our ability to manage research and development and other operating expenses consistent with our expected revenue growth over the next twelve-months;
- Our ability to fund and achieve benefits from our increased focus on internal research and development and external alliances as well as our ability to capitalize on opportunities across our businesses;
- Our ability to develop products and technologies successfully in addition to our TAXUS drug-eluting stent technology;
- Our failure to succeed at, or our decision to discontinue, any of our growth initiatives;
- Our ability to integrate the acquisitions and other strategic alliances we have consummated;
- Our decision to exercise options to purchase certain strategic alliances and our ability to fund with cash or common stock these and other acquisitions; and
- The timing, size and nature of strategic initiatives, market opportunities and research and development platforms available to us and the ultimate cost and success of these initiatives.

## **International Markets**

- Increasing dependence on international sales to achieve growth;
- Risks associated with international operations including compliance with local legal and regulatory requirements; and
- The potential effect of foreign currency fluctuations and interest rate fluctuations on our revenues, expenses and resulting margins.

## Liquidity

- Our ability to generate sufficient cash flow to fund operations and capital expenditures, as well as our strategic investment and share repurchase programs over the next twelve months and to maintain borrowing flexibility beyond the next twelve months;
- Our ability to access the public capital market and to issue debt or equity securities on terms reasonably acceptable to us;
- Our ability to incur a 24 percent effective tax rate, excluding certain charges, during the remainder of 2005 and to recover substantially all of our deferred tax assets; and
- Our ability to align expenses with future expected revenue levels and reallocate resources to support our future growth.

### Other

 Risks associated with significant changes made or to be made to our organizational structure or to the membership of our executive committee.

Several important factors, in addition to the specific factors discussed in connection with each forward-looking statement individually, could affect our future results and growth rates and could cause those results and rates to differ materially from those expressed in the forward-looking statements contained in this report. These additional factors include, among other things, future economic, competitive, reimbursement and regulatory conditions, new product introductions, demographic trends, intellectual property, financial market conditions and future business decisions made by us and our competitors, all of which are difficult or impossible to predict accurately and many of which are beyond our control. Therefore, we wish to caution each reader of this report to consider carefully these factors as well as the specific factors discussed with each forward-looking statement in this report and as disclosed in our filings with the SEC. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this report.

## ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our currency risk consists primarily of foreign currency denominated firm commitments, forecasted foreign currency denominated intercompany and third-party transactions and net investments in certain subsidiaries. We use both nonderivative (primarily European manufacturing operations) and derivative instruments to manage our earnings and cash flow exposure to changes in currency exchange rates. We had currency derivative instruments outstanding in the contract amount of \$3,924 million at September 30, 2005 and \$4,171 million at December 31, 2004. The decrease in the outstanding amount is primarily due to the maturity of hedge contracts. We recorded \$116 million of other assets and \$40 million of other liabilities to recognize the fair value of these derivative instruments at September 30, 2005 as compared to \$70 million of other assets and \$129 million of other liabilities recorded at December 31, 2004. A 10 percent appreciation in the U.S. dollar's value relative to the hedged currencies would increase the derivative instruments' fair value by \$153 million at September 30, 2005 as compared to \$163 million at December 31, 2004. A 10 percent depreciation in the U.S. dollar's value relative to the hedged currencies would decrease the derivative instruments' fair value by \$186 million at September 30, 2005 as compared to \$190 million at December 31, 2004. Any increase or decrease in the fair value of our currency exchange rate sensitive derivative instruments would be substantially offset by a corresponding decrease or increase in the fair value of the hedged underlying asset, liability or cash flow.

Our earnings and cash flow exposure to interest rate changes on U.S. dollar and Japanese yen denominated borrowings is partially offset by interest rate changes on U.S. dollar denominated cash investments. We use interest rate derivative instruments to manage our exposure to interest rate movements either by converting floating-rate

borrowings into fixed-rate borrowings or fixed-rate borrowings into floating-rate borrowings. We had interest rate derivative instruments outstanding in the notional amount of \$1,100 million at September 30, 2005 and \$1,600 million at December 31, 2004. The decrease in the notional amount is due to the maturity of hedge contracts related to our \$500 million 6.625 percent senior notes that we repaid upon maturity during March 2005. We recorded \$31 million of other assets and \$4 million of other liabilities to recognize the fair value of our interest rate derivative instruments at September 30, 2005 as compared to \$32 million of other assets and \$1 million of other liabilities recorded at December 31, 2004. A one percent increase in interest rates would decrease the derivative instruments' fair value by \$77 million at September 30, 2005 as compared to \$84 million at December 31, 2004. A one percent decrease in interest rates would increase the derivative instruments' fair value by \$83 million at September 30, 2005 as compared to \$92 million at December 31, 2004. Any increase or decrease in the fair value of our interest rate sensitive derivative instruments would be substantially offset by a corresponding decrease or increase in the fair value of the hedged borrowings.

## ITEM 4. CONTROLS AND PROCEDURES

### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation of our President and Chief Executive Officer and Executive Vice President - Finance & Administration and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2005 pursuant to Rule 13a-15(b) of the Securities Exchange Act. Disclosure controls and procedures are designed to ensure that material information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and ensure that such material information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. Based on their evaluation, our Chief Executive Officer and Chief Financial Officer concluded that as of September 30, 2005, our disclosure controls and procedures were effective.

## **Changes in Internal Controls over Financial Reporting**

During the quarter ended September 30, 2005, there were no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# PART II OTHER INFORMATION

## ITEM 1. LEGAL PROCEEDINGS

Note H - Commitments and Contingencies to our unaudited condensed consolidated financial statements contained elsewhere in this Quarterly Report is incorporated herein by reference.

## ITEM 2. UNREGISTERED SALES OF SECURITIES AND USE OF PROCEEDS

The following table provides information about our purchases of our equity securities that are registered pursuant to Section 12 of the Exchange Act during the third quarter ended September 30, 2005:

			Total # of Shares Purchased as Part of	Maximum # of Shares that May Yet Be
	Total # of Shares	Average Price Paid	Publicly Announced	Purchased Under the
Period	Purchased (1)	Per Share	Programs (2)	Programs
7/1/05-7/31/05	1,200,300	\$28.65	1,200,300	38,462,100
8/1/05-8/31/05	1,192,700	28.57	1,192,700	37,269,400
9/1/05-9/30/05			w	37,269,400
Total	2,393,000	\$28.61 (3)	2,393,000	37,269,400

The information regarding securities authorized for issuance under our equity compensation plans required by this Item is included below.

- (1) We purchased all shares on the open market or through privately negotiated transactions to provide shares for general corporate purposes, including issuances pursuant to our equity incentive plans or acquisitions and strategic alliances.
- (2) Between 1993 and September 2004, our Board of Directors authorized us to repurchase 119,630,000 shares (on a split-adjusted basis) of our common stock. As of October 2004, there were 22,724,000 shares remaining under this repurchase authorization. On October 26, 2004, we announced that our Board of Directors authorized us to repurchase an additional 50,000,000 shares of our common stock, which brought our total number of shares that could be repurchased to 72,724,000. At the end of the third quarter of 2005, 37,269,400 shares of our common stock are remaining under this repurchase authorization. Our repurchase program does not have an expiration date.
- (3) Weighted average price paid per share.

## ITEM 6. EXHIBITS

- 31.1 Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 31.2 Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
- 32.1 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, President and Chief Executive Officer
- 32.2 Certification Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Executive Vice President and Chief Financial Officer

## **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized on November 8, 2005.

## **BOSTON SCIENTIFIC CORPORATION**

By: /s/ Lawrence C. Best

Name: Lawrence C. Best

Title: Executive Vice President - Finance & Administration and Chief Financial Officer

## CERTIFICATE OF SERVICE

I, Jack B. Blumenfeld, hereby certify that on January 3, 2006, I caused to be electronically filed with the Clerk of the Court Exhibits to the Opening Brief in Support of Conor's Motion to Stay using CM/ECF, which will send notification of such filing(s) to the following:

Josy W. Ingersoll Young, Conaway, Stargatt & Taylor, LLP

and that I caused copies to be served upon the following in the manner indicated:

## **BY HAND**

Josy W. Ingersoll Young, Conaway, Stargatt & Taylor, LLP 1000 West Street, 17<sup>th</sup> Floor Wilmington, DE 19899

## BY FEDERAL EXPRESS

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/s/ Jack B. Blumenfeld (#1014)
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